

Attorney Docket No.: KUZ0027US.NP
Inventors: Shirouzu et al.
Serial No.: 10/561,499
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REMARKS

Claims 1-13 are pending in the instant application. Claims 3, 8 and 13 have been withdrawn from consideration by the Examiner. Claims 1-2, 4-7 and 9-12 have been rejected. Claims 1, 2, 6 and 7 have been amended, claim 5 has been canceled, without prejudice, and new claims 14-19 have been added. Support for these amendments is provided in the original claims and in the specification at, for example, page 4, line 7 through page 6, line 5, and page 6, lines 24-25. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Species Election Requirement

The Examiner made final the species election mailed August 27, 2007 suggesting there was no allowable generic or linking claim. Accordingly, the Examiner has withdrawn from consideration claims 3, 8 and 13.

It is respectfully pointed out, however, that linking claim 1 has been amended and is believed to be in condition for allowance. Accordingly, rejoinder and examination of previously-withdrawn claims 3, 8 and 13 which depend from claim 1 is respectfully requested.

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II. Rejection of Claims 1-2, 4-7 and 9-12 under 35 U.S.C. 103(a)

Claims 1-2, 4-7 and 9-12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2002/0086039) in view of Kimura et al. (U.S. Patent 6,133,327), Kuhner et al. (US 2003/0194445), Packman (U.S. Patent 4,945,084), Blackman (U.S. Patent 4,873,265), and Mekata (U.S. Patent 6,581,807).

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 1 has been amended to recite that the anti-trichophyton drug is one kind selected from butenafine hydrochloride, terbinafine hydrochloride, benzylamine type, and thiocarbamic acid type antifungal agents, and is present in an amount that is 0.1 - 10% by mass.

The cited combination of references does not disclose, suggest, or predict the preparation recited in amended claim 1 or claims dependent therefrom.

References of Kimura et al. (U.S. Patent 6,133,327), Kuhner et al. (US 2003/0194445), Packman (U.S. Patent 4,945,084), Blackman (U.S. Patent 4,873,265), and Mekata (U.S. Patent 6,581,807) are silent with respect to any anti-trichophyton drugs.

Lee also provides no teaching of the anti-trichophytions as set forth in amended claim 1. While Lee mentions

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inclusion of terbinafine hydrochloride in foot care products, it is only as an inactive ingredient. See paragraph [0224] at page 19. Thus, any further rejection based on Lee is unmerited because Lee clearly teaches that the presence of terbinafine hydrochloride is not a result-effective variable. Further, Lee discloses no particular amount of terbinafine hydrochloride. In contrast, claim 1 as amended specifically requires between 0.1% and 10% anti-trichophyton. This missing range limitation cannot be satisfied by the cited art where the variable in question (here terbinafine hydrochloride) is not taught to be a result-effective variable. See specifically M.P.E.P. § 2144.05 (II) (B) which states:

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

The case law is clear; the prior art references must teach or suggest all of the particular limitations of the

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claims. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim."). Clearly, the cited combination of references, which does not teach as an active ingredient an anti-trichophyton drug selected from butenafine hydrochloride, terbinafine hydrochloride, benzylamine type, and thiocarbamic acid type antifungal agents, and present in an amount that is 0.1 - 10% by mass, cannot teach or suggest all the limitations of the invention as now claimed.

New claims 14-19 are also unobvious over the cited combination of references.

With respect to claims 14 and 15, Applicants respectfully disagree with the Examiner's suggestion that Mekata teaches, suggests or predicts in any way the use of an anti-inflammatory such as glycyrrhetinic acid in a foot treatment preparation. Mekata teaches an aerosol container that may contain many different types of products, but none of its teachings indicate that any such products would, or should, be combined. The Examiner cites the disclosure of "inflammation inhibitors such as... glycyrrhetinic acid" for

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use in such container, see col. 5, line 36, as part of a long list of many, many other chemicals, but nothing suggests that any of them be used in a foot medicament or treatment. Similarly, the Examiner relies on col. 7, lines 28-33, which recites that the aerosol container can be used to contain, among many of its separate uses, "products for human organism[,]" which include everything from "a medicine for athlete's foot" to "insect repellant" to "a hair dye". Indeed, this varied list also alternately includes "an anti-inflammatory". However, this disclosure in no way suggests that such anti-inflammatory be combined with a medicine for athlete's foot any more than it suggests the combination of any of these varied compounds with a "hair dye" or a "drug for asthma[.]" See *id.*

The inclusion of a "medicine for athlete's foot" together with "an anti-inflammatory" in such a varied list of separately-used compounds rather tends to teach against their combination in the same aerosol canister. As such, Applicants respectfully submit that new claims 14 and 15, as well as original claims 9 and 12 which also include this limitation, are allowable over the cited combination of art references.

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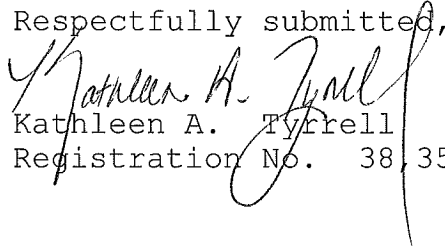
Applicants further submit with respect to new claims 16-19 that the cited combination of references does not teach, suggest or predict an external preparation for athlete's foot treatment, *consisting essentially of* an anti-trichophyton drug mixed with at least one compound selected from l-menthol, menthol analogue compounds and bactericidal compounds, wherein the anti-trichophyton drug is selected from butenafine hydrochloride, terbinafine hydrochloride, benzylamine type, and thiocarbamic acid type antifungal agents, and is present in an amount that is 0.1 - 10% by mass, nor an external preparation for athlete's foot treatment, *consisting essentially of* an anti-trichophyton drug mixed with at least one compound selected from l-menthol, menthol analogue compounds and bactericidal compounds and at least one kind of, one or more of, a local anesthetic, an antihistamine and an anti-inflammatory drug, wherein the anti-trichophyton drug is selected from butenafine hydrochloride, terbinafine hydrochloride, benzylamine type, and thiocarbamic acid type antifungal agents, and is present in an amount that is 0.1 - 10% by mass.

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Accordingly, for all of the foregoing reasons, it is respectfully requested that the rejection under 35 U.S.C. 103(a) be withdrawn and that claims 1-4 and 6-21 be allowed.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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